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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/428,122	10/27/1999	ANDREW D. MURDIN	19721-007-(P)	4261

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[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

1645

DATE MAILED: 08/20/2003

25

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No. <b>09/428,122</b>	Applicant(s) <b>Murdin et al.</b>	
Examiner <b>S. Devi, Ph.D.</b>	Art Unit <b>1645</b>	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1)  Responsive to communication(s) filed on Apr 3, 2003
- 2a)  This action is FINAL.      2b)  This action is non-final.
- 3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

- 4)  Claim(s) 1-4, 10-14, 16, 18, 19, 25, 26, 38, 39, and 42-44 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5)  Claim(s) \_\_\_\_\_ is/are allowed.
- 6)  Claim(s) 1-4, 10-14, 16, 18, 19, 25, 26, 38, 39, and 42-44 is/are rejected.
- 7)  Claim(s) \_\_\_\_\_ is/are objected to.
- 8)  Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9)  The specification is objected to by the Examiner.
- 10)  The drawing(s) filed on \_\_\_\_\_ is/are a)  accepted or b)  objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12)  The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13)  Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All b)  Some\* c)  None of:

1.  Certified copies of the priority documents have been received.
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

- 14)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a)  The translation of the foreign language provisional application has been received.
- 15)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1)  Notice of References Cited (PTO-892)
- 2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3)  Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_
- 4)  Interview Summary (PTO-413) Paper No(s). 19 & 20.
- 5)  Notice of Informal Patent Application (PTO-152)
- 6)  Other: Sequence search report.

## **DETAILED ACTION**

### **Continued Prosecution Application**

- 1) The request filed on 04/03/2003 (paper no. 22) for a Continued Prosecution Application (C.P.A) under 37 C.F.R 1.53(d) based on parent Application, SN 09/428,122, is acceptable and a C.P.A has been established. An action on the C.P.A follows.

### **Applicants' Amendment**

- 2) Acknowledgment is made of Applicants' amendment filed 04/03/03 (paper no. 23) in response to the final Office Action mailed 10/09/02 (paper no. 18). With this, Applicants have amended the specification.

### **Status of Claims**

- 3) Claims 1, 4 and 13 have been amended via the amendment filed 04/03/03.  
Claims 40 and 41 have been canceled via the amendment filed 04/03/03.  
Claims 1-4, 10-14, 16, 18, 19, 25, 26, 38, 39 and 42-44 are pending and are under examination.

### **Co-pending Applications**

- 4) Several co-pending applications exist in the Office that include one or more inventors of the instant application and the chlamydial polynucleotides. These applications have been identified previously. It is noted that Applicants have made the following statement on page 5 of their amendment filed 12/04/01:

However, Applicants agree to provide the Examiner copies of the requested claims upon determination of allowable subject matter in the present application.

### **Prior Citation of Title 35 Sections**

- 5) The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office Action.

### **Prior Citation of References**

- 6) The references cited or used as prior art in support of one or more rejections in the instant Office Action and not included on an attached form PTO-892 or form PTO-1449 have been previously cited and made of record.

### **Specification**

7) On page 40, line 16, the address of the American Type Culture Collection is incorrect. Effective 23 March 1998, ATCC has a new address: 10801 University Boulevard, Manassas, VA 20110-2209. Amendment to the specification is suggested to reflect this. It is suggested that Applicants examine the whole specification to make similar correction to the address, wherever it appears.

**Rejection(s) Moot**

8) The rejection of claims 40 and 41 made in paragraph 14(d) of the Office Action mailed 10/09/02 (paper no. 18) is moot in light of Applicants' cancellation of the claims.

**Objection(s) Withdrawn**

9) The objection to claim 1 made in paragraphs 14(a), 14(b) and 14(c) of the Office Action mailed 10/09/02 (paper no. 18) is withdrawn in light of Applicants' amendment to the claim.

**Rejection(s) Moot**

10) The rejection of claims 40 and 41 made/maintained in paragraph 11 of the Office Action mailed 10/09/02 (paper no. 18) under 35 U.S.C § 112, first paragraph, as being non-enabled, is moot in light of Applicants' cancellation of the claims.

11) The rejection of claims 40 and 41 made in paragraphs 12(b) and 12(c) of the Office Action mailed 02/25/02 (paper no. 15) under 35 U.S.C § 112, second paragraph, as being indefinite, is moot in light of Applicants' cancellation of the claims.

**Rejection(s) Withdrawn**

12) The rejection of claim 1 made in paragraph 12(a) of the Office Action mailed 10/09/02 (paper no. 18) under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

13) The rejection of claims 2-4, 10-14, 16, 18, 25, 26, 38, 39 and 42-44 made in paragraph 12(c) of the Office Action mailed 02/25/02 (paper no. 15) under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the base claim.

14) The rejection of claims 1-4, 10-14, 16, 18, 19, 25, 26, 38, 39 and 42-44 made/maintained in paragraph 22 of the Office Action mailed 02/25/02 (paper no. 15) and paragraphs 11 and 13 of the Office Action mailed 10/09/02 (paper no. 18) under 35 U.S.C § 112, first paragraph, as being non-enabled, is withdrawn.

**Rejection(s) under 35 U.S.C § 112, Second Paragraph**

**15)** Claims 1-4, 10-14, 16, 18, 19, 25, 26, 38, 39 and 42-44 are rejected under 35 U.S.C § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

(a) Claim 1 is vague and indefinite in the recitation ‘polynucleotide, when administered in an immunogenically-effective amount to a mammal, induces an immune response in said mammal against said strain of *Chlamydia*’, because it is unclear to what part or antigen of the chlamydial strain the immune response is directed to: polynucleotide, polypeptide, an intracellular antigen, or an extracellular antigen? If the immune response is polynucleotide-specific, it is unclear how would it be effective against ‘said strain of *Chlamydia*’, since the polynucleotide is intracellular and therefore inaccessible to the antibodies or immune cells.

(b) Claims 2-4, 10-14, 16, 18, 19, 25, 26, 38, 39 and 42-44 are also rejected as being indefinite because of the indefiniteness or vagueness identified above in the base claim.

**Rejection(s) under 35 U.S.C § 112, First Paragraph**

**16)** Claim 1 and those claims dependent therefrom are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Base claim 1, as amended, includes the new limitation: ‘a polynucleotide that has a complementary sequence to’ SEQ ID NO: 1. However, there appears to be no descriptive support in the specification, as originally filed, for such a limitation. Applicants have not pointed to a specific part of the specification that provides descriptive support for the newly added phrase. Therefore, the above-identified limitation(s) in the claims is considered to be new matter. *In re Rasmussen*, 650 F2d 1212 (CCPA, 1981). New matter includes not only the addition of wholly unsupported subject matter but also, adding specific percentages or compounds after a broader original disclosure, or even omission of a step from a method. See M.P.E.P 608.04 to 608.04(c). MPEP 2163.06 states that Applicants should specifically point out the support for any amendments made to the disclosure.

Applicants are respectfully requested to point to the descriptive support in the specification as filed, for the newly added limitation(s), or to remove the new matter from the claim(s).

**Rejection(s) under 35 U.S.C § 102**

- 17) The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language.

- 18) Claims 1-3, 10-14, 16-19, 25, 26, 38, 39 and 42 are rejected under 35 U.S.C § 102(e) as being anticipated by Knudsen *et al.* (WO 98/58953).

Knudsen *et al.* disclosed a DNA sequence that shows more than 90% structural sequence identity with the instantly recited SEQ ID NO: 1, an expression vector and a eukaryotic or human muscle cells, prokaryotic or bacterial host cell, or recombinant bacteria, such as *E. coli*, or a living microbial vaccine comprising the same. Diagnostic kits comprising one or more nucleic acid fragments are taught. See the attached sequence alignment; and pages 8, 20, 21, 26, 27, 45 and 46 of Knudsen *et al.* The DNA sequence and the protein encoded by the same are used as vaccine components. The vaccine effects *in vivo* expression of the protein in a mammal, such as, a human, to whom it is administered and confers substantially increased resistance to infections with *Chlamydia pneumoniae* (see abstract; and pages 20, 21 and 26). The gene is operably linked to a promoter and is expressed in fusion with a second DNA (see pages 21 and 22; and Example 2). The prior art DNA sequence of such a length and such a high sequence identity is expected to hybridize under the recited hybridizing conditions with the polynucleotide recited in part (b) of claim 1. That the prior art DNA would have the recited function, i.e., the ability to induce an immune response against the chlamydial strain is inherent from the teachings of Knudsen *et al.*

Claims 1-3, 10-14, 16, 18, 19, 25, 26, 38, 39 and 42 are anticipated by Knudsen *et al.*

**Rejection(s) under 35 U.S.C. § 103**

- 19) The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are

such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 148 USPQ 459, that are applied for establishing a background for determining obviousness under 35 U.S.C. § 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or unobviousness.

20) Claims 42, 43 and 44 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Knudsen *et al.* (WO 98/58953) in view of Murdin *et al.* (US 6,403,101).

Claim 42 has been included in this rejection only to the extent that claims 43 and 44 include the limitation 'claim 42'.

The references of Knudsen *et al.* or Murdin *et al.* are used in this rejection because they qualify as prior art under subsection (e) of 35 U.S.C. § 102 and accordingly are not disqualified under U.S.C 103(a).

The disclosure of Knudsen *et al.* is explained above, which does not expressly teach adenoviral or alphaviral vector, or a *Shigella* or *Salmonella* vector.

However, the use of such viral or bacterial vaccine vectors was conventional in the art for the expression of a chlamydial nucleic acid. For instance, Murdin *et al.* taught that chlamydial polynucleotides can be recombinantly expresses in live adenoviral or alphaviral vector, *Shigella* or *Salmonella* vectors (see column 5, second paragraph).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to use Murdin's adenoviral vector or *Salmonella* vector to express Knudsen's polynucleotide to produce the vaccine vector of the instant invention, with a reasonable expectation of success, because it was conventional in the art to use an adenoviral or a *Salmonella* vector to express a chlamydial polynucleotide, as shown by Murdin *et al.* The use of alternative and art known live vectors for expression of an art-known polynucleotide is well within the realm of routine experimentation.

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Claims 42, 43 and 44 are *prima facie* obvious over the prior art of record.

**Remarks**

- 21) Claims 1-4, 10-14, 16, 18, 19, 25, 26, 38, 39 and 42-44 stand rejected.
- 22) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center located in Crystal Mall 1. The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The CM1 facsimile center receives papers 24 hours a day, seven days a week. The RightFax number for submission of before-final amendments is (703) 872-9306. The RightFax number for submission of after-final amendments is (703) 872-9307.
- 23) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (703) 308-9347. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.45 a.m to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

August, 2003

S. DEVI, PH.D.  
PRIMARY EXAMINER